

Appl. No. : 09/859,651
Filed : May 17, 2001

REMARKS

Claim 48 has been cancelled with this amendment. Claims 41, 49, 53, 58, and 63 have been amended. Claims 41-47 and 49-64 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

The specific changes to the specification and the amended claims are shown on a separate set of pages attached hereto and entitled **VERSION WITH MARKINGS TO SHOW CHANGES MADE**, which follows the signature page of this Amendment. On this set of pages, insertions are underlined and deletions are struck through.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 41-64 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is believed to be overcome by Applicants' claims amendments. Amendments have been made to clarify the claimed subject matter as suggested by the Examiner.

Regarding the Examiner's comments on page 4 of Paper No. 8 with respect to claim 63, Applicants would like to clarify that, in practice, two separate and distinct strains of *E. coli* are used and are not mixed. Claim 63 has been amended to clarify this point. Support for the amendment is found in the examples. See Example 3, for instance.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 20, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 41, 49, 53, 58, and 63 have been amended as shown.

Claim 41. (Currently amended) A method for producing a soluble ~~biologically~~ biologically- active protein, comprising:

transforming an *E. coli* host cell with a plasmid having at least one copy of an expressible eukaryotic gene encoding said protein;

lytically infecting the transformed bacterial host cell with a bacteriophage λ having cI_{857} , Q_{am117} , and R_{am54} mutations; and

cultivating the *E. coli* host cell under a culture condition that induces lytic growth of said cell without lysis ~~until a desired level of production of said protein is reached,~~ wherein said protein is produced as to produce the a soluble, biologically-active protein.

Claim 49. (Currently amended) A method for producing a soluble ~~biologically~~ biologically- active protein, comprising:

transforming an *E. coli* host cell with a plasmid having at least one copy of an expressible eukaryotic gene encoding said protein;

lytically infecting the transformed bacterial host cell with a bacteriophage λ having cI_{857} , Q_{am117} , and R_{am54} mutations, wherein the bacteriophage also contains at least one copy of said expressible gene encoding said protein; and

cultivating the *E. coli* host cell under a culture condition that induces lytic growth of said cell without lysis ~~until a desired level of production of said protein is reached,~~ wherein said protein is produced as to produce the a soluble, biologically-active protein .

Claim 53. (Currently amended) A method for producing a biologically active protein, comprising:

transforming an *E. coli* host cell with a plasmid having at least one copy of an expressible eukaryotic gene encoding said protein;

lytically infecting the transformed bacterial host cell with a bacteriophage λ having at least one mutated gene selected from the group consisting of N, Q, and R; and ~~providing conditions to delay lysis;~~ and

cultivating the *E. coli* host cell under a culture condition that induces lytic growth of said cell without lysis ~~until a desired level of production of said protein is reached to~~ produce the biologically active protein.

58. (Currently amended) A method for producing a biologically active protein, comprising:

transforming an *E. coli* host cell with a plasmid having at least one copy of an expressible eukaryotic gene encoding said protein;

lytically infecting the transformed bacterial host cell with a bacteriophage λ , having at least one mutated gene selected from the group consisting of N, Q, and R, wherein the bacteriophage also contains at least one copy of said expressible gene encoding said protein; and

~~providing conditions to delay lysis; and~~

cultivating the *E. coli* host cell under a culture condition that induces lytic growth of said cell without lysis ~~until a desired level of production of said protein is reached.~~

63. (Currently amended) A method of producing a ~~biologically~~ biologically-active protein comprising:

growing a first strain of *E. coli* cells, which harbor a strain of bacteriophage λ , wherein the bacteriophage λ has a temperature-sensitive mutation,

manipulating the temperature to provide for lysis of the first strain of *E. coli* cells and release of the bacteriophage λ ,

adding the released bacteriophage λ to a second strain of *E. coli* cells to lytically infecting ~~a the~~ second strain of *E. coli* cells with the released bacteriophage λ , wherein said second strain of *E. coli* cells has been transformed with a plasmid having at least one copy of an expressible gene encoding said biologically-active protein; and

culturing the second strain of *E. coli* host cells such that said biologically-active protein is produced and released to the media, ~~wherein said protein is produced as a~~ soluble, biologically-active protein.